



Trends-in-Medicine

July 2005

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Quick Pulse

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EYECARE UPDATE

To check on trends in the eyecare field, an industry expert and 22 ophthalmologists (refractive surgeons) were interviewed about the outlook for refractive surgery, and 63 optometrists were asked for their perspective on refractive surgery referrals as well as issues relating to contact lenses, age-related macular degeneration (AMD), and dry eye therapies.

LASIK

Most sources reported that LASIK procedures are down in July, but they described it as the usual summer slowdown, and they expect procedures to pick up again in a month or so.

Thirteen of the 22 refractive surgeons questioned said they are doing fewer operations this summer due to patient travel and post-operative restrictions that restrict summer activities such as swimming. Only two surgeons described the slowdown as greater than usual (down more than 10%-20%).

- *Texas*: “We see a slowdown every summer.”
- *Louisiana*: “We’re seeing the normal summer slowdown. It’s not greater than usual, but we usually do 130 to 140 cases a month. In June it was down to 110, so it was down about 20%. It will pick up again in September.”
- *Florida #1*: “If anything, the slowdown would be related to people in South Florida getting out of town for a few weeks.”
- *California*: “I don’t see anything atypical; there is seasonality in LASIK that varies from region to region, practice to practice.”
- *Florida #2*: “June was a little slower than average, down about 25%, but July has been busier than usual so far.”

According to Dave Harmon of Market Scope (www.mktsc.com), there was a “good” increase in LASIK procedures in the first quarter of 2005 and probably a small increase – in the low, low single digits – in the second quarter. So far, Harmon has not revised his outlook down for the year, which is 1.43 million procedures, which would be up 6%-8% over last year.

Some of the refractive surgeons said they are beginning to see growth in refractive procedures other than LASIK. This includes:

- **Accommodating IOLs**, such as Alcon’s ReStor, Advanced Medical Optics’ (AMO’s) ReZoom, and Eyeonics’ Crystalens.
- **Clear lens exchange with phakic IOLs** (also known as ICLs), such as AMO’s Verisyse or Staar Surgical’s Visian.
- **Refractec’s Conductive Keratoplasty (CK).**

Surgeon comments on these other refractive procedures included:

- *Missouri*: “We’re seeing a dramatic increase in the number of CK, IOLs, and clear lens exchange because we market those in the summer to compensate for the expected LASIK slowdown.”
- *California*: “The biggest impact has been from the Crystalens. It’s now our method of choice for all patients over 50 years of age.”
- *West Coast*: “(There is an impact) due to the increase in clear lenses, with the approval of ReStor and ReZoom. They were 50% of our refractive surgery volume in June.”
- *California #2*: “For the high myopes where we may be doing no-cut LASIK, now we can consider phakic IOLs.”
- *Louisiana*: “I have resisted the CK procedure because of the track record it had with the Sunrise (Hyperion LTK) system. Even though this is a different procedure, they’ve gone to the light touch, and they’re claiming more stable results. I think it might open up a group of patients that I currently discourage from having surgery – those with normal distance vision who are interested in getting rid of their dependence on reading glasses. Everyone says CK gets a wider zone and multifocal cornea, and you don’t induce as much myopia in the distance. We’re finally thinking of getting a unit and giving it a shot.” He also has resisted clear lens exchange because of the risk of retinal detachments but sees a future for multifocal implants for certain patients: “Some patients in the past were discouraged...With multifocal capacity you can get rid of myopia and hopefully get rid of reading glasses; this is another viable option.”
- *Staar investigator*: “I have 20 patients waiting for it (Staar’s phakic IOL) to be approved...My bias is against the Verisyse lens. I don’t like making a 6.5 mm incision and suturing it. Hopefully, Staar will get its act together. People have been waiting four to five years. These are all high myopes – all at least -10 diopters and some up to -20 diopters. I like the elegance of the procedure, the fact that you don’t see the lens in the eye; it’s very cosmetically unnoticeable, and you don’t have to suture...It’s also easier to remove if you need to, and it looks great in the eye.”
- *California #3*: “I see patient confusion. CK is temporary and has a long way to go to become a serious player against the LASIK market, but it appeals to patients. The lens implants are more invasive and only ideal for extreme prescriptions. The phakic lens only commands a small market, as of right now. Clear lens exchange could be the exciting new option. More patients are asking for it, but cost is the stumbling block because of the ASC (ambulatory surgery center) costs or OR (operating room) costs.”

- *Texas*: “The only effect is from presbyopic lens surgery; we often upgrade patients older than 40 to this technology.”

However, Harmon said these procedures do not appear to be cutting into LASIK volume, “The numbers are still really small. Mainly, they are patients who are not LASIK candidates to begin with. Most of the patients getting the Alcon’s ReStor and AMO’s ReZoom lenses are cataract patients because of the change in the Medicare reimbursement rule (which now allows patients to pay for the extra cost of more advanced lenses). That may change over time, but it is what I’m seeing now.”

In line with this, two-thirds of surgeons said they have seen no impact on LASIK volume from other refractive procedures. Rather, they said those other procedures are an adjunct to LASIK surgery.

- *California #1*: “LASIK is still the most versatile refractive surgery. Other procedures help patients who are not candidates for LASIK; they don’t replace LASIK.”
- *California #2*: “There is no impact from alternative procedures. People seem to want LASIK, Wavefront, and IntraLase (IntraLase Corp.)”
- *Florida*: “These are procedures which are complementary to LASIK. They don’t replace LASIK but serve as options for patients who are not good candidates for LASIK. I haven’t had any patients ask about CK. I have performed a few phakic IOLs this summer on patients who came in for LASIK, but were not candidates for it. I haven’t had anyone ask about refractive lens exchange.”
- *West Coast*: “I see no impact at all. These procedures extend the range of treatable refractive conditions or refractive errors rather than encroaching on the share treatable and appropriate for LASIK.”
- *New York*: “If anything, they are synergistic, in a sense.”
- *Illinois*: “They’re not cutting into LASIK. They’re giving other people, who weren’t LASIK candidates, opportunities for surgery. It’s more additive than subtractive.”
- *Minnesota*: “We’ve done very few keratoplasty procedures. We’re not doing the phakic IOLs or clear lens exchanges yet.”

A few surgeons mentioned using the IntraLase FS laser for LASIK. With traditional LASIK, a microkeratome is used to create a thin flap in the cornea. With IntraLase, the microkeratome is replaced with a laser that creates the flap with energy pulse applied to the eye. A West Coast doctor said, “We’ve been using the IntraLase for three years, and I

still like it. We get patients from doctors who can't guarantee their flaps are thin enough. It's a more elegant way to make flaps, more predictable, with better results. It doesn't get them out of glasses but it makes them potentially able to be fit with contacts. The only other option is a transplant; this is a step short of corneal transplant, and allows the patient to buy more time. So IntraLase will be a growing percentage of the market. It's still small numbers; not millions a year, but it's a nice little niche for the company." An Illinois surgeon said, "LASIK is at a high point with IntraLase and custom cornea treatments. It's better than ever, but there's still room for improvement." An optometrist added, "Even if the patient chooses a blade (microkeratome), it's nice to offer IntraLase."

Compared to 2004, optometrists say their referrals for LASIK are generally flat, but a third of sources said they are more likely to refer a patient for refractive surgery if the surgeon uses IntraLase to make the flap. One commented, "Those who wanted LASIK have gotten it, and the incessant marketing by surgeons in the mass media causes patients to bypass the optometrist." Another said, "Most of my patients are presbyopes, and they hold back (on LASIK) because they will not be free of glasses after spending \$4,000-\$5,000." A third said, "There has been a decrease in referrals because my patients balk at the cost. They are waiting for insurance to cover it (Hah!)."

Optometrists also reported that patient interest is up in phakic IOLs and clear lens exchange. They said they have no preference for either AMO's Verisyse or Staar's Visian lenses for refractive surgery. One commented, "I am not comfortable with iris-fixated IOLs."

Contact Lenses

Optometrists said that during 2004 use of all the major brands of contact lenses increased: Bausch & Lomb, Novartis/Ciba Vision, CooperVision, and Johnson & Johnson/Vistakon, but B&L increased the least of these. For 2005, Ciba Vision and CooperVision are expected to have the most increase, with B&L use up but not as much, and Vistakon lens use flat. Comments about specific companies included:

- **Bausch & Lomb.** A doctor said, "I'm using more B&L because of Purevision." Another doctor said, "I'm using less B&L because there are no new products."
- **Ciba Vision.** A doctor said, "My use is increasing because of the O₂Optix." Another said, "My use is increasing because of the Night & Day lenses, which are good for dry eyes."
- **CooperVision.** A doctor said, "My use is increasing because they are doctor-friendly and the sales rep is excellent." Another source said, "My use is increasing due to the merger with Ocular Sciences." Another said, "My use is decreasing because they don't have a silicone hydrogel."

- **Vistakon.** One doctor said, "My use decreased because of dryness and a poor sales rep." Another said, "My use is decreasing this year because my colleagues and I are mad at Vistakon." A third said, "My use is down because of the price." A fourth said, "My use is increasing because of new lenses coming out."

Vistakon sales reps got the highest rating by far, CooperVision reps were in the No. 2 position, and B&L and Ciba Vision reps were further down the scale and tied for third. In toric lenses, the preferred provider is far and away CooperVision, and optometrists plan to increase their use of those lenses. Doctors predicted a slight increase in use of B&L torics, but use of other torics is expected to be flat.

A slim majority of optometrists said enthusiasm for two-week silicone hydrogel lenses is growing. Silicone hydrogel lenses allow more oxygen to pass through to the eye than do traditional PMMA contact lenses, which in turn let patients wear the lenses longer and more safely.

Optometrists rated Johnson & Johnson/Vistakon's Acuvue Advance and Ciba Vision's O₂Optix – both two-week lenses – as the best. A doctor commented, "O₂Optix is popular because of the comfort and ease of insertion and removal. Acuvue Advance is easy to sell because of all the advertising." Another said, "Patients like these lenses because they can sleep in them for a longer time." A third added, "Patients prefer the Acuvue Advance due to the comfort."

Sources did not believe Bausch & Lomb's Purevision lens (a silicone hydrogel lens approved for 30-day wear) would ever be a big trend, for a variety of reasons, but the key factor cited was lack of comfort. One doctor wondered, "Would you want to wear your underwear for 30 days? Why would you want to do that to your cornea?" Another said, "I don't fit too many silicone hydrogels because my patients don't like them. They say they are uncomfortable. There is an adjustment period with them. At first, many patients can feel the lens and have a lens sensation in their eye. Theoretically, that is supposed to go away, but I have many patients who don't get past that point, and they don't continue to wear them. You really have to push silicone hydrogels. Really high myopes who sleep in their lenses will suffer through it, but not many other patients. Patients who come in as a new fit see the commercials on TV and are programmed by the commercials. They are the ones who want to sleep in them. And cost is an issue. Silicone hydrogels are a little more expensive." A third optometrist said, "Purevision is not a dinosaur, but it lost momentum when it was pulled from the U.S. market and other lenses stepped in."

Yet, use of Purevision, which first gained FDA approval in 2001 but had to be taken off the U.S. market after B&L lost a patent dispute, is picking up. A doctor said, "There was a lot of time off, but people *loved* it once." Another commented, "I was looking forward to its return to the market; I missed it."

A third optometrist said, "I'll use Purevision because I like B&L." A fourth said, "Most optometrists are scared to give patients 30-day extended wear lenses." A fifth added, "It will gain traction because it handles well, fits comfortably, and is a monthly-wear."

The only major contact lens company without a silicone hydrogel lens is CooperVision. But among these doctors CooperVision is not losing much, if any, market share. A Florida doctor said, "I've not heard of anyone pulling away (from CooperVision)."

Age-related Macular Degeneration (AMD)

On average, these optometrists see 27 *dry* AMD patients each month. They feel there is a real need to treat these patients, and a few are recommending nutritional treatments.

Rheopheresis is a double-filtration plasma pheresis therapy for dry AMD that purportedly eliminates high-molecular weight proteins, including fibrinogen, a₂-macroglobulin, LDL, fibronectin, von Willebrand factor, and perhaps multimeric vitronectin. It also reduces blood and plasma viscosity. It is an outpatient therapy that takes about three hours to perform.

After hearing a lecture on Rheopheresis, many optometrists were convinced that it has promise, but very few thought it would become a practice builder. Two doctors called Rheopheresis "snake oil," but one said he is beginning to become convinced it may work, "I've been to several seminars. It seems that if you treat the blood and get more oxygen and nourishment to the tissues, the result might improve."

Optometric Opinion of Rheopheresis

Opinion	Responses
Promising/very excited	43%
Cautious optimism	7%
Dubious	25%
Unsure	25%

Optometrists said they generally refer patients to a retinal specialist early, at the first sign of any vision loss. Most said they expect that the new treatments available to treat *wet* AMD will encourage them to refer patients even sooner.

Dry Eye (keratoconjunctivitis sicca)

The dry eye therapy most frequently recommended by these optometrists is artificial tears, especially Allergan's Refresh, Alcon's Natural Tears, and Alcon's Systane. Only about 10% commonly use punctal plugs for dry eye, but almost 25% regularly prescribe Allergan's Restasis (cyclosporine ophthalmic emulsion 0.05%). Compared to six months ago, 60% are using more Restasis, 34% are using the same amount, and 6% are using less Restasis. A doctor commented, "No

one treatment works for every patient." Another said, "It is not first-line because there are so many cheaper alternatives."

On average, 14% of the optometric dry eye patients are on Restasis. More than twice as many patients (32%) try Restasis but discontinue it, on average, after 2.2 months. Optometrists said that patients stop taking Restasis primarily because of the cost, but other factors include lack of efficacy, stinging/irritation, and compliance. On average, 82% of doctors said they reserve Restasis for the most difficult patients because of the cost.

Sample availability also has been a problem for 25% of sources. Side effects, lack of efficacy, and container size were mentioned as problems by only a few sources. However, Allergan's direct-to-consumer campaign is boosting both patient acceptance of Restasis and physician willingness to prescribe it. Over the next year, most optometrists expect their use of Restasis to increase.

Among the comments about Restasis were:

- "I used it myself and stopped due to burning/discomfort and lack of symptom improvement."
- "I work in a managed care setting, and patients are limited to \$150 a month for meds. Also getting the drops on our formulary and availability of meds is limited."
- "I don't use Restasis because punctal plugs work much better."
- "Cost is not the issue. The problem is that it isn't on all drug formularies."
- "I give a sample, and I intend to give a prescription at follow-up, but they (patients) don't come back."
- "Patients are too lazy to use drops even four times a day and too cheap to stay with Restasis twice a day."
- "Patient education is the problem. Most patients don't know this is a chronic condition, and they expect to be cured in one week."
- "I use Restasis for 25%-40% of my dry eye patients – the ones I think can afford it."

Several new treatments are in development for dry eye, and doctors almost all agreed that there is a real need for new agents. The key problems with existing treatments is lack of efficacy, frequency of administration, patient compliance, cost and need for long-term use. A Florida doctor said, "The whole treatment is just so cumbersome, not predictable and costly to the patient. The idea of using something for three to four months to see if it works just sounds too dubious to the patient."

Few of these sources were not familiar with Inspire's diquafosol (INS-365). Most had no opinion of it and could

not say how it compares to Restasis or artificial tears. They also did not have a good idea of which patients would be the best candidates. One doctor commented, "It was rejected twice by the FDA. No one (no patient) knows or asks about it."

Medicare Part D Drug Benefit

In January 2006 Medicare will add a drug benefit (Part D). Optometrists are divided on whether this will affect their use of glaucoma, dry eye, or other eye drops: 45% predicted it will, 42% said it won't, and 13% were unsure. One source commented, "Medicare's drug benefit is a joke. With the cost of premiums and the deductible, one might as well not have the benefit." Another said, "Medicare always seems to set a standard, and we use it in all our price settings. And HMOs and PPOs use Medicare standards." A third commented, "Compliance may actually increase, and I think, generally, lots of patients will actually get eye exams if they had one in the past and were diagnosed, but dropped off treatment. It may also mean we can prescribe more expensive drugs." A New England optometrist said, "Insurance already dictates what patients are willing to pay for because of their co-pays. Medicare may have a preferred formulary which will limit which meds our patients will accept."

